

EXHIBIT 35

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

IN RE NATIONAL PRESCRIPTION OPIATE
LITIGATION

This document relates to:

Track One Cases

MDL No. 2804

Case No. 17-md-2804

Hon. Dan Aaron Polster

DECLARATION OF COLLEEN MCGINN

I, Colleen McGinn, declare, upon personal knowledge and under penalty of perjury, that the following is true and correct:

Professional History

1. I am the Senior Director of DEA Compliance at Teva Pharmaceuticals USA, Inc. ("Teva USA") and have served in this role since October of 2015.
2. I began working at Cephalon, Inc. ("Cephalon") in April of 2004 as a manager of controlled substances. Prior to working at Cephalon, I had more than a decade of experience in DEA compliance on both the distribution and manufacturing sides. I served as DEA Compliance Manager at Siegfried USA (from 1991 until 2002) and then as Compliance Manager at Cardinal Health (from 2002 until 2004).
3. In October of 2011, Teva USA became affiliated with Cephalon and I became an employee of Teva USA.

4. I have personal knowledge of the materials stated herein.

Cephalon's Suspicious Order Monitoring ("SOM") Program

5. I have personal knowledge of Cephalon's compliance program regarding diversion, including its SOM program, from April 2004. Cephalon has always been committed

to preventing the diversion of controlled substances, including opioids, that it manufactured and sold. Since at least 2004, Cephalon had a DEA compliance department, and had controls in place to prevent the theft or diversion of opioids, including controls to ensure the proper manufacturing, storage, treatment, and handling of controlled substances.

6. Cephalon also had a system in place to identify, monitor, investigate, and, if necessary, report suspicious orders of the only two opioids it manufactured and sold (Actiq and Fentora) to the Drug Enforcement Administration (“DEA”). Given the narrow FDA-approved indications for these brand opioid medicines, they accounted for a very small amount of overall opioid sales nationwide. Orders for Actiq and Fentora were placed by very few customers—all of which had a longstanding relationship with Cephalon. In addition, Cephalon had only one distributor for Actiq and Fentora: a Cardinal Health affiliate that was a DEA registrant.

7. Cephalon had a system to review orders to identify any that might be suspicious and to require further investigation and reporting. Additionally, the Cardinal Health affiliate also reviewed all of the orders Cephalon received through its own system, as it was required to do as a DEA registrant. Cephalon’s system was integrated with Teva USA’s SOM system after Cephalon became affiliated with Teva USA in October 2011. I am not aware of any suspicious order placed with Cephalon that should have been, but was not, brought to the attention of the DEA, much less any such order for an opioid shipment into Ohio (or elsewhere).

8. The DEA has never communicated to Cephalon that its SOM system did not comply with applicable law or that Cephalon failed to report suspicious orders of controlled substances. In addition, the DEA has not taken any enforcement action against Cephalon for any alleged failure to maintain controls against diversion or to report suspicious orders of controlled substances.

Teva USA's SOM Program

9. I also have personal knowledge of Teva USA's compliance program regarding diversion, including its SOM program, since at least October 2012. Based upon my experience, Teva USA is and has been committed to preventing diversion of controlled substances. When I joined Teva USA, it had a DEA Compliance department. Likewise, I am aware that prior to my joining Teva USA, Teva USA had controls in place to prevent the theft or diversion of opioids, including controls to ensure the proper manufacturing, storage, treatment, and handling of controlled substances.

10. Teva USA has maintained and currently maintains a SOM system to identify, monitor, investigate, and, if necessary, report suspicious orders to the DEA. In addition, the vast majority of Teva USA's customers have been and currently are wholesale distributors. Teva USA understands that its customers have their own SOM systems in place to identify, monitor, investigate, and, if necessary, report suspicious orders from their customers to the DEA. Teva USA expected that its customers were complying with their legal obligations with respect to suspicious orders. Teva USA conducts a thorough investigation of any new customer that seeks to purchase controlled substances, including opioids, from the company.

11. Teva USA has long used computer software technology to aid its efforts to combat diversion. When I started working at Teva USA, it used a computer-based algorithm (known as "SORDS") as part of its SOM program. Teva USA further updated and enhanced that algorithm-based system in late 2012 (known as "SORDS II"). That system, among other things, compiled average purchase quantities for each customer for each ordered product, set upper control limits based on the average sales data, and automatically pended orders that deviated from the customer's normal purchasing pattern while an investigate took place. If the

order was justified after investigation, the DEA compliance team would release the order. Any order deemed “suspicious” would be reported to the DEA.

12. In 2014, Teva USA developed a new and enhanced computerized order review system, called the Defensible Order Pending System (“DefOPS”), which Teva USA implemented in early 2015. This system runs a proprietary algorithm against every order for any controlled substance, and certain non-controlled substances, to identify specific orders that should be reviewed, analyzed, and further investigated by the DEA Compliance team to determine whether they are “suspicious” in accordance with applicable law. That system remains in place today, though Teva USA continues to update that system.

13. Teva USA has identified and reported orders to the DEA that were suspicious, after investigation by the company into the circumstances of the order. Prior to approximately August 2016 (when Teva USA became affiliated with the former generic subsidiaries of Allergan plc), Teva USA received a smaller number of orders for opioid medicines. I am not aware of any suspicious order placed with Teva USA that should have been, but was not, brought to the attention of the DEA, much less any such order for an opioid shipment into Ohio (or elsewhere).

14. In 2012, Teva USA hired Cegedim Compliance Solutions (“Cegedim”) to review Teva USA’s SOM system (“SORDS”) at the time. In September of 2012, Cegedim issued a document stating that Teva USA has the “essential elements” for an SOM program, but identified potential areas of improvement in an attempt to be retained as a consultant by Teva USA and to have Teva USA utilize its proprietary SOM system. Teva USA decided not to use Cegedim as a consultant primarily because Cegedim refused to disclose its methodology in developing its algorithm, which would have deprived Teva USA of the ability to analyze the

efficacy of its system or to understand any changes that needed to be made. Teva USA also had concerns about the security of Cegedim's cloud-based system. This decision was not made simply to save costs. Teva USA implemented its SORDS II program shortly after it received the Cegedim document.

15. The DEA has never communicated to Teva USA that its SOM system did not comply with applicable law or that Teva USA failed to report suspicious orders of controlled substances. In addition, the DEA has not taken any enforcement action against Teva USA for any alleged failure to maintain controls against diversion or to report suspicious orders of controlled substances.

Pursuant to 28 U.S.C. § 1746(1), I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated: July 25, 2019

By:



Colleen McGinn